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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,199	10/17/2001	Gregory P. Pogue	42202	4164

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EXAMINER
HELMER, GEORGIA L

ART UNIT	PAPER NUMBER
1638	12

DATE MAILED: 07/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/978,199	Applicant(s) POGUE ET AL.	
	Examiner Georgia L. Helmer	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *1-4 and 11-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 May 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *9* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Restriction election

1. The Office acknowledges the receipt of Applicant's restriction election, Paper No. 11, filed 15 May 2003. Applicant elects Group II, directed to Claims 5-10, with traverse.

Applicant traverses, saying that if one considers "virus proteins" as the only protein specifically described in the claim, then one is producing bovine lysozyme, the same protein produced by the method of Group III. If the Examiner is referring to the viral coat protein, this is a deminimus example and a frivolous use of the claimed RNA molecule. And that the only example given by the Examiner is not a practical alternative use that uses the unique claimed properties of the claimed product. Accordingly withdrawal of the restriction requirement, at least with respect to Groups II and III and substantive examination of claims 5-11 together, is requested. Applicant's traversal has been considered and is unpersuasive because the Group II and III are related as product and process of use, and the product as claimed can be used in a materially different process of using the product. The Group II product—recombinant RNA viruses—can be used as a source of viral proteins. Therefore restriction is proper and is made Final.

2. Claims 1-32 are pending. Claims 5-10 are examined in this action. Claims 1-4 and 11-32 are withdrawn as being drawn to non-elected inventions. This restriction is made FINAL.

Information Disclosure Statement

3. An initialed and dated copy of Applicant's IDS form 1449, Paper No. 9 , filed 12 July 2002 is attached to the instant Office action.

Specification

4. Applicant is required to update the status (pending, allowed, etc.) of all parent priority applications in the first line of the specification. The status of all citations of US filed applications in the specification should also be updated where appropriate. The provisional application is not mentioned here.

Drawings

5. The following informality has been noted and requires correction in response to this Office Action. Figure 3 is described as figure 3/2, in the Brief Description of the Drawings. Since figures must be numbered separately, i.e. "Figure 1A," "Figure 1B," Applicant is required to amend the Brief Description of the Drawings accordingly to reflect the proper figure designations.

Claim Rejections - 35 USC § 112-second

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 6, 8, and 10 are rejected under 35 U.S.C. 112-2nd.

In claim 6, the relationship of SEQ ID NO: 1 to the nucleotide sequence encoding bovine lysozyme of claim 5, is not clear. Is the SEQ ID NO: 1 of claim 6 in addition to the nucleotide sequence of claim 5.

Claim 6 is drawn to "the plant virus of claim 5 ...comprising SEQ ID NO: 1". However, the plant virus of claim 5 is an RNA virus, whereas SEQ ID NO: 1 is a DNA sequence. This is ambiguous and need to be clarified.

Claim 8 is drawn to "the RNA molecule of claim 7...comprising SEQ ID NO: 1". However, claim 7 is drawn to an RNA molecule, whereas SEQ ID NO: 1 is a DNA sequence. This is ambiguous and need to be clarified.

Claim 10 is drawn to "the tobamovirus of claim 9 ...comprising SEQ ID NO: 1". However, claim 9 is drawn to a recombinant tobamovirus, whereas SEQ ID NO: 1 is a DNA sequence. This is ambiguous and needs to be clarified.

Clarification/correction is required.

Claim Rejections - 35 USC § 112-1 written description.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 5-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to a recombinant RNA plant virus comprising a nucleotide sequence encoding bovine lysozyme, where the plant virus comprises SEQ ID NO: 1, to an RNA molecule comprising a first viral subgenomic promoter, a second viral subgenomic promoter, and a bovine lysozyme coding sequence under control of either the first or the second viral subgenomic promoter, where the coding sequence is SEQ ID NO: 1, to a recombinant comprising a nucleotide sequence encoding bovine lysozyme, where the bovine lysozyme is SEQ ID NO: 1. However, no recombinant RNA plant viruses, no RNA molecules comprising a first viral subgenomic promoter, a second viral subgenomic promoter, and a bovine lysozyme coding sequence under control of either the first or the second viral subgenomic promoter, and no recombinant tobamoviruses are described.
The specification does not disclose what biological or structural features would be present in the recombinant RNA plant viruses, the RNA molecules comprising a first viral subgenomic promoter, a second viral subgenomic promoter, and a bovine lysozyme coding sequence under control of either the first or the second viral subgenomic promoter, or the recombinant tobamoviruses. Applicants are claiming a

genus of sequences, yet there is no description of the structural features that define the genus.

See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed, Cir. 1997), where it states: "The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA . . . Accordingly, the specification does not provide a written description of the invention . . ."

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, one skilled in the art would not have been in possession of the genus claimed at the time this application was filed.

Claim Rejections - 35 USC § 112-Enablement

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant's claims are drawn to a recombinant RNA plant virus comprising a nucleotide sequence encoding bovine lysozyme, where the plant virus comprises SEQ ID NO: 1, to an RNA molecule comprising a first viral subgenomic promoter, a second

viral subgenomic promoter, and a bovine lysozyme coding sequence under control of either the first or the second viral subgenomic promoter, where the coding sequence is SEQ ID NO: 1, and to a recombinant tobamovirus comprising a nucleotide sequence encoding bovine lysozyme, where the bovine lysozyme is SEQ ID NO: 1.

Enablement is considered in view of the *Wands* factors (MPEP 2164.01(a)). The enablement issues are: a recombinant RNA plant virus, an RNA molecule and a recombinant tobamovirus.

The state of the art and the predictability or lack thereof in the art: The state of the art is such that one skilled in the art can readily make DNA constructs. RNA can be produced *in vitro* or *in vivo*, with the in vitro and in vivo systems having different requirement. RNA synthesis requires a template, which may be RNA or DNA, and the appropriate regulatory elements. RNA production from DNA requires signals for initiation, termination, processing, and specification of the reading frame for coding sequences, among other things. It is unpredictable that any RNA produced from a DNA template would the desired RNA.

Guidance and working examples: Applicant recites a nucleic acid molecule (Example 1) encoding bovine lysozyme (this molecule not described, see supra, 112-1 Written Description, above), inoculation of *Nicotiana* (Example 2, page 18) with "tobacco mosaic virus vector expressing bovine lysozyme" (which is not described, see supra, 112-1 Written Description, above), extraction of bovine lysozyme and purification of

bovine lysozyme, and turbidimetric assays of bovine lysozyme enzymatic activity (Example 3). Applicant has no examples of a recombinant RNA plant virus, an RNA molecule or a recombinant tobamovirus.

While working examples are not required, Applicant must provide sufficient guidance to address the all the issues discussed above. Without such guidance, the experimentation required would not be routine, but would be undue.

In view of the breadth of the claims (any recombinant RNA plant virus, any RNA molecule and any recombinant tobamovirus), the lack of guidance, the unpredictability of the art, undue trial and error experimentations would be required to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 5 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Mirkov, et. al. US # 5,850,025, issued 15 December 1998.

Mirkov teaches a recombinant RNA plant virus (col 11, lines 15-24) comprising bovine lysozyme (col 5, lines 1-23 and col 9, lines 12-23).

Accordingly Mirkov anticipates the claimed invention.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 5-10 are rejected under 35 U.S.C. 103(a) as being obvious over Mirkov, et. al. US # 5,850,025, issued 15 December 1998, in view of Donson, et. al., US # 5,318,931, issued 31 May 1994.

Mirkov teaches a recombinant RNA plant virus (col 11, lines 15-24) comprising bovine lysozyme (col 5, lines 1-23 and col 9, lines 12-23).

Mirkov does not teach a recombinant RNA molecule comprising a first viral subgenomic promoter , a second viral subgenomic promoter and a bovine lysozyme coding sequence under control of either the first or the second subgenomic promoter.

Donson teaches recombinant tobamoviruses (claims 9, 10, 33 and 34), and plant viral subgenomic promoters (col 4, lines 65 bridging to col 5, line 8) controlling non-native coding sequences.

Donson provides motivation to substitute the bovine lysozyme of Mirkov for the proteins of Donson (col 12, lines 23-40). Therefore, it would be obvious to use the invention in plants.

Accordingly, Mirkov in view of Donson renders obvious the claimed invention.

Remarks

15. SEQ ID NO: 1 is known in the prior art.

16. No claim is allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 703-308-7023. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service, whose telephone number is 703-308-0196

ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1600

Georgia Helmer PhD
Patent Examiner
Art Group 1638
July 11, 2003